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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,453	11/28/2003	James C. Peacock III	53233-00007	9909

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EXAMINER	
DOWE, KATHERINE MARIE	
ART UNIT	**PAPER NUMBER**
3734	

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09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,453	PEACOCK, JAMES C.	
	Examiner	Art Unit	
	Katherine M. Dowe	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a complete response the amendment filed 7/2/07.

2. Claims 1-46 are currently pending.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-7, 12, 13, 17, 34-37, 39, 43, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakayama (US 2006/0036311). Nakayama discloses a stent comprising a scaffold from a third material (11; para 0057), a porous surface (12) on the stent comprising a first material and a plurality of pores (para 0062), and a second composite material comprising a plurality of particles located within the pores and composed of a bioerodable polymer material in combination with a bioactive agent (para 0066-0067). The particles may be less than 1 micron in diameter and may have an outer diameter substantially equivalent to the inner diameter of the pores. The bioactive agent may comprise an anti-restenosis agent, anti-inflammatory agent, anti-proliferative agent, or growth factor (para 0067). The third material forming the stent scaffold may comprise a stainless steel alloy, a nickel-titanium alloy, or a cobalt-chromium alloy (para 0058). The first material is not inherently porous and the pores are formed at discrete locations by laser cutting (para 0080). The pores comprise an inner diameter of about 5 microns (para 0062).

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 8-10 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama (US 2006/0036311), as applied to claim 1 above. Regarding claims 8-10, Nakayama discloses the invention substantially as claimed including a porous surface (12) on the stent. However, Nakayama discloses the pore diameter ranges from 5-500 microns and thus does not disclose specifically disclose the pore diameter is less than about 1 micron. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the range to extend to less than about 1 micron, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 40-42, Nakayama disclose the second composite material located within the pores is composed of a bioerodable polymer material in combination with a bioactive agent (para 0066-0067). However, Nakayama does not disclose the ratio of bioactive material to bioerodable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Nakayama such that the second composite material was formed with a ratio of bioactive material to bioerodable material to be at least 0.5:1, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

7. Claims 11, 14-16, 18-33, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama (US 2006/0036311), as applied to claims 1 and 17 above, in view of Gertner et al. (US 2003/0060873). Regarding claim 11, Nakayama discloses the invention substantially as claimed first material comprising a plurality of pores (12). However, Nakayama discloses the material is not inherently porous and the pores are formed at discrete locations by laser cutting (para 0080). Gertner et al. disclose a similar device comprising a stent comprising a scaffold, a porous surface on the stent comprising a first material and a plurality of pores, and a second material comprising a bioactive agent located within the pores. However Gertner et al. disclose alternate methods of manufacturing the porous first material including using a material, such as a ceramic, that is inherently porous (0044). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Nakayama such that the first material was inherently porous to simplify the manufacturing process by eliminating the step of forming the pores by laser cutting.

Regarding claim 14 and 15, Nakayama does not disclose the pores are photochemically etched into the first material. Gertner et al. disclose an alternate method for forming pores including using a substrate comprising a sacrificial material that may be removed by etching (para 0044). Thus forming pores where the material has been removed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Nakayama such

that the pores were formed by photochemical etching instead of using a laser such that the pores may be formed by readily available manufacturing methods.

Regarding claims 16 and 18, Nakayama does not disclose the first material comprises a non-polymeric sintered material. Gertner et al. disclose a similar porous outer surface and disclose sintered metallic structures could be used as an alternative to polymeric structures (para 0009). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Nakayama such that the first material comprised a sintered metallic material such that pores may be created during the sintering process and as such the additional method step forming pores by laser cutting would not be necessary.

Regarding claims 19-28, 45, and 46, Nakayama disclose the invention substantially as claimed including a stent comprising a scaffold from a third material (11; para 0057), a porous surface (12) on the stent comprising a first material and a plurality of pores (para 0062), and a second composite material comprising a plurality of particles located within the pores and composed of a bioerodable polymer material in combination with a bioactive agent (para 0066-0067). The third material forming the stent scaffold may comprise a stainless steel alloy, a nickel-titanium alloy, or a cobalt-chromium alloy (para 0058). However Nakayama does not disclose the first material comprises an electrochemically deposited material. Gertner et al. disclose a similar device comprising a stent comprising a scaffold, a porous surface on the stent comprising a first material and a plurality of pores, and a second material comprising a bioactive agent located within the pores using an alternate first material. The first

material is an electrolessly electrochemically deposited metallic matrix (para 0048) and thus comprises a metal and a reducing agent of the metal (para 0036, 0057). The metal may comprise nickel or cobalt and the reducing agent may comprise phosphorus (para 0056, 0064). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Nakayama such that the first material was composed of an electrolessly deposited material such as nickel or cobalt with phosphorous. Gertner et al. disclose it is difficult to fully incorporate bioactive agents into structures that have previously had pores formed therein, such as sintered structures (para 0009). Alternatively, by forming the first porous material by electroless electrochemical deposition, the bioactive material can be stored in the pores at a greater concentration (para 0041). Thus, this method would allow the Nakayama device to incorporate a greater concentration of bioactive material to improve the drug delivering capacity of the device.

Regarding claims 29-33, Nakayama does not disclose fourth and fifth materials may be included between the first porous material and the third material forming the stent structure. Gertner et al. teach a fourth material may be formed between the stent, or third material, and the coating, or second material, and a fifth material may be formed between the fourth material and the coating, or second material, since a plurality of layers may be formed with coating layers between metallic layers (para 0063). The fourth material may be electroplated metal such as nickel (para 0029, 0036, 0064), the fifth material may be a layer of electrolessly electrochemically deposited composite with metal and a reducing agent of the metal (0056-0058), and the coating, or first material,

may be another layer of electrolessly electrochemically deposited composite with metal and reducing agent of the metal with the composite material (0051). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Nakayama such that the stent system comprised a fourth layer of electroplated nickel and a fifth layer of electrolessly electrochemically deposited material comprising a metal and its reducing agent between the stent and the second material. Furthermore, it would have been obvious to modify the second material such that it was composed of an electrolessly electrochemically deposited material comprising a metal and its reducing agent. The additional layers would provide additional pores to provide a greater amount of bioactive agent. Furthermore, the by electroless electrochemical deposition would allow the Nakayama device to incorporate a greater concentration of bioactive material in each pore to improve the drug delivering capacity of the device.

8. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama (US 2006/0036311), as applied to claim 1 above, in view of Wang et al. (US 2007/0037739). Nakayama discloses the invention substantially as claimed including a stent comprising a scaffold from a third material (11; para 0057), a porous surface (12) on the stent comprising a first material and a plurality of pores (para 0062), and a second composite material comprising a plurality of particles located within the pores and composed of a bioerodable polymer material in combination with a bioactive agent (para 0066-0067). Furthermore, the bioactive agent may comprise an anti-restenosis

agent, anti-inflammatory agent, anti-proliferative agent, or growth factor (para 0067). However, Nakayama does not disclose the bioactive agent may comprise des-aspartate angiotensin 1. Wang et al. disclose compounds useful in coating stents to treat restenosis including des-aspartate angiotensin 1 (para 0040, 0253-0261) which has been shown to substantially inhibit smooth muscle cell proliferation and drastically reduce restenosis (para 0261). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Nakayama such that the bioactive agent may also comprise des-aspartate angiotensin 1. Thus, the marketability of the device would increase and the stent may be more effective by effectively reducing restenosis.

Response to Arguments

9. Applicant's arguments, see amendment, filed 7/20/2007, with respect to the rejection(s) of claim(s) 1-46 under Gertner et al. have been fully considered and are persuasive. Applicant argues Gertner et al. do not teach the porous surface material and the composite material are two distinctly different materials. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Nakayama (US 2006/0036311).

10. Applicant's arguments filed 7/20/2007 have been fully considered but they are not persuasive. Applicant argues Gertner et al. do not teach the first material is inherently porous. The Examiner respectfully traverses the Applicants remarks.

Gertner et al. disclose the first material may be composed of a ceramic (para 0044), which is inherently porous.

Applicant additionally argues Gertner et al. do not teach the pores are chemically etched into the first material. The Examiner respectfully traverses the Applicant's remarks. Gertner et al. disclose the first material may comprise a substrate comprising a sacrificial material. When the first material is subjected to etching, the sacrificial material is removed, thus leaving voids or pores.

Finally, Applicant argues Gertner et al. do not teach a ratio of bioactive material to bioerodable material of at least 0.5:1. The Examiner respectfully traverses the Applicant's remarks. Gertner et al. discloses an electroless deposition process controls the percentage of bioactive material by adjusting the pH, temperature, and the constituents accordingly. Furthermore, Gertner et al. is capable of having a ratio of bioactive material to bioerodable material of at least 0.5:1. Applicant should include structural limitations to patentably distinguish the bioactive agent percentage capability of the instant application over the prior art.

11. In response to applicant's argument that using a stent formed from a cobalt chromium alloy presents additional benefits such as enhanced strength and biocompatibility as well as corporation into a cobalt-based electrochemical deposition, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
September 12, 2007

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER